4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Steatohepatitis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research in cosponsorship with the American Association for the Study of Liver Diseases (AASLD) is announcing a 2-day public workshop entitled "Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic fatty liver disease (NAFLD)." There are no approved treatments for NAFLD and its complications of nonalcoholic steatohepatitis (NASH) and liver fibrosis and cirrhosis. This workshop will provide a forum to discuss trial design, including endpoints for clinical trials in NAFLD, to promote efficient drug development in this area and thus improved treatments for patients.

Date and Time: The public workshop will be held on September 5 and 6, 2013, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, in the Great Room (room 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Anissa Davis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5016, FAX: 301-796-9904, email: Anissa.Davis@fda.hhs.gov.

Registration: There is no fee to attend the public workshop, but attendees must register online at http://www.aasld.org/additionalmeetings/Pages/aasldfdanash.aspx before September 1, 2013. (FDA has verified this Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.) Space is limited, and registration will be on a first-come, first-served basis. Those without Internet access should contact Anissa Davis (see Contact Person) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Anissa Davis (see Contact Person) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: This workshop will provide a forum to discuss the key issues in the design of clinical trials of drugs for the treatment of liver disease secondary to NAFLD. Stakeholders, including industry sponsors, those from academia, patients with NAFLD-

associated liver disease, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in clinical trials. Trial design strategies and possible candidates for endpoints will be explored. The state of knowledge of the natural history of NAFLD will also be discussed.

Dated: July 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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